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EXAMINER	
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1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,318	TIETZ, RODNEY L.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,5,7-10,12,13,15 and 17-23* is/are allowed.

6)☒ Claim(s) *3, 6, 11, 14, 16, 24, 25, and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to claim 26 is withdrawn, in light of its cancellation.

3. The rejections of claims 2 and 15-20 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim amendments or upon further consideration.

Claim Objections

4. Claims 6 and 11 are objected to because of the following informalities: The claims refer to Tables 5 and 6 in the specification as showing SSR and isozyme typing profiles, respectively. However, these profiles are shown in Tables 6 and 7, respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 3, 14, 16, and 27-30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed June 30, 2003. Applicants traverse the rejection in the paper received September 30, 2003. Applicant's arguments have been fully considered but were not found persuasive.

In response to the rejection of claim 3, Applicant argues that while claim 2 is directed to a population of seed of corn variety I390185, it is not necessary that the population be essentially homogeneous. Applicant provides the definition for "population" from the Merriam-Webster on-line dictionary (Exhibit A), and argues that the relevant definition is "a body of persons or individuals having a quality or characteristic in common." Applicant also provides the definition for "homogeneous" (Exhibit B), which is "of uniform structure or composition throughout," and argues that a population of seed of corn variety I390185 could be non-uniform in size or shape, yet have the common quality of being a corn plant of variety I390185. Applicant argues that as such, claim 3 is in proper dependent form and is not indefinite. (response, page 8).

Applicant appears to be arguing that the recitation, "essentially homogeneous," in claim 3 indicates that the individual I390185 seeds of the claimed population share a uniform structure, for example size and shape. However, the issue does not concern the size and shape of individual seeds. Further, Applicant's argument is inconsistent with the discussion of "essentially homogeneous population of inbred seed" in the specification. Page 5, lines 15-21, of the specification states, "Essentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed. Most preferably, an essentially homogeneous population of inbred corn seed will contain between about 98.5%, 99%, 99.5% and about 99.9% of inbred seed, as measured by seed grow outs." This definition does not concern the size and shape of the particular inbred seed of an essentially homogeneous population

of inbred seed, but rather addresses the percentage of the population that is made up of the particular inbred seed versus other varieties of seed. The recitation, "A population of seed of the corn variety I390185" in claim 2 indicates that the population of claim 2 is a homogeneous population of seed of corn variety I390185. The scope of claim 3 is unclear because, in light of the specification, the essentially homogeneous population of that claim can comprise varieties of seed other than I390185, whereas the population of claim 2 is directed to a single variety of seed, that of corn variety I390185. Applicant's argument also indicates that the members of the population of claim 2 have the common quality of being a corn plant of variety I390185. Amending claim 3 to read "An essentially homogeneous population of corn seeds consisting essentially of the seed of claim 1", would obviate this rejection.

In response to the rejection of claim 14, Applicant argues that a population need not be essentially homogeneous (response, page 9, 1st full paragraph). However, the claim clearly states, "An essentially homogeneous population of corn plants..."

Applicant again argues that a population of plants grown from I390185 seed could vary in size or other characteristics due to environmental or other conditions, but still be population produced by growing I390185 seed (response, page 9, 1st full paragraph).

However, again, Applicant's interpretation of "essentially homogeneous population" differs from that provided on page 5, lines 15-21 of the specification, which explains how other varieties of seed may be in an essentially homogeneous population of a particular variety of seed. It is rather well known in the art, when referring to plants, that the term "variety" is used to distinguish genetically distinct taxonomic groups below

the species level. I390185 is a variety of corn plant. Corn plant "X" is another variety of corn plant, and is genetically distinct from variety I390185. I390185 seed cannot produce "X" corn plants, but can only produce I390185 corn plants. It is not clear why Applicant is arguing that an "essentially homogenous population of corn plants" refers to the non-uniform nature of the same variety of corn plant, when the definition in the specification (page 5, lines 17-20) concerns the amounts of genetically different varieties of corn that can be in an essentially homogeneous population. Claim 14 indicates that growing only the seed of the inbred corn plant I390185 produces the corn plants of the essentially homogeneous population of corn plants. But if only one variety of seed is being grown, only one variety of corn plant can be produced. It therefore remains unclear why claim 14 is directed to an essentially homogeneous population of corn plants that, according to the specification, can comprise more than one variety of plant. If the population of claim 14 is to encompass only plants produced by growing I390185 seeds, as Applicant appears to be arguing, it is not clear why the claim is directed to an essentially homogeneous population of corn plants. The definition on page 5 of the specification also indicates that an essentially homogenous population of an inbred corn seed may be comprised of 100% of that seed. However, limitations of the specification cannot be read into the claims. Amending claim 14 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I390185, a sample of said seed having been deposited under ATCC Accession No. PTA-4493" would obviate this rejection.

In response to the rejection of claims 16 and 27: Applicant argues that claim 16 adds a gene conferring male sterility, while claim 27 adds a single locus conversion, to the parent claim. Applicant argues that the claims contain a reference to the parent claim, contain a further limitation of the subject matter claimed in the main claim, and incorporate all elements of the claim from which they depend. Applicant argues that how the plants acquire the added elements is irrelevant to the scope or definiteness of the claims, as they are product claims, not process or product by process claims (response, paragraph bridging pages 9-10).

However, the claims do not incorporate all elements of their parent claims. The plant of claim 15 is male fertile. The plant of claim 16, however, is not male fertile. Therefore, claim 16 does not incorporate all elements of the claim from which it depends. Further, as the plant of claim 15 is male fertile, it is contradictory to say that claim 16 incorporates all elements of claim 15, yet is directed to a plant that is not male fertile. The single locus conversion of the plant of claim 27 does not have to be a gene that confers male sterility. However, as the locus may encode any trait, and can affect the plant of parent claim 5 in any manner, the plant of claim 27 does not have to have all of the traits expressed by the plant of claim 5. The plant of claim 27 then would not have all of the limitations of the plant of claim 5. Claim amendments are suggested at the end of this Office action.

In response to the rejection of claim 28, Applicant notes that the single locus may or may not have been directly inserted into the genome of the claimed plant, and argues that this does not render the claim indefinite, because the single locus may have been

inserted into a parent I390185 plant and self pollinated to produce the claimed plant. Applicant argues that the single locus need not have been directly inserted into the genome of I390185, and that loci that are stably inserted into a corn genome are also stably inherited (response, page 10, last paragraph).

However, a parent plant of inbred variety I390185 is itself I390185. Therefore it remains unclear, what other genomes are encompassed by "a corn genome", and how does it relate to the plant of claim 28? Further, if the single locus is transformed into an entirely unrelated plant and introduced into I390185 by crossing and selection, the resultant plant would have the single locus but it would not otherwise be exactly the same as I390185.

6. Claims 6, 11, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 11: the recitation, "in accordance with" renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

In claim 30: the recitations, "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

7. Claims 24, 25, 27-31 remain and claims 6 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 30, 2003. Applicant traverses the rejection in the paper received September 30, 2003. Applicant's arguments were considered but were not found fully persuasive. The rejection is withdrawn from claims 2-4 and 14 upon further consideration.

Applicant argues that the hybrid seeds and plants of claims 24 and 25 are described because they have I390185 as a parent and therefore contain a copy of the same genome as corn plant I390185, and that they have inherited half of their genetic material from I390185 (response, page 12, 1st full paragraph). It is maintained that the claimed hybrids will not have the same morphological and physiological characteristics as I390185. I390185 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by I390185. That all hybrids will inherit half of their alleles from I390185 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I390185 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I390185, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each

parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I390185 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if I390185 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the expression of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of one-half of the hybrid's genetic complement being inherited from I390185 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Applicant also argues that the entire genetic contribution of corn plant I390185 is described by way of deposit of seed of I390185 with the ATCC, and believes that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support, Applicant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material (response, page 12, 1st full paragraph). However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the

case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. Here, as in *Enzo*, the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I390185 seed. The function of the plant grown from an I390185 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from I390185. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited I390185 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I390185 seed, as discussed above.

Applicant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Applicant argues that here, all of the members of the claimed genus of hybrids having I390185 as one parent share the identical feature of having the genetic complement of I390185 (response, paragraph bridging pages 12-13). However, in *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the function (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the genetic complement of I390185. Furthermore, the genetic complement of

the other unknown parent has not been described, and hence Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I390185 with any and all other inbred or hybrid corn plants.

Applicant argues that the claimed F1 hybrid plants having I390185 as one parent will share the same genetic complement from I390185, and are readily identifiable by the genetic marker analysis in Tables 6 and 8. Applicant argues that hybrid corn plant 0004555 has the SSR genetic marker profile of I390185 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I390185 as one parent, save for "an occasional difference at a locus due to spontaneous genetic rearrangements" (response, page 13, 1st full paragraph). However, while all of the claimed hybrids will inherit the SSR marker profile of I390185, they will not inherit the same genetic markers from the other parent as did hybrid 0004555, because they will have different parents, having different markers. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 0004555 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I390185 to any other corn plant. One skilled in the art cannot identify the morphological and physiological characteristics of corn plant 0004555 that will be expressed by all other members of the genus, nor can one identify the characteristics that will be different.

Further, while hybrid 0004555 has inherited the SSR marker profile of I390185, the specification does not describe the traits that are correlated with these markers. The traits expressed by 0004555 are not solely due to the presence of the alleles associated with the SSR markers inherited from the I390185 genome, or the genetic contribution of

I390185, as discussed above. Further, written descriptions of each of the SSR and isozyme markers are not provided. The markers represent specific nucleotide sequences. While the markers are named, this is not sufficient to describe the nucleotide sequences that they represent. Further, none of these markers have been linked to any expressed traits.

Claims 6 and 11 have been added to the rejection. It is noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile. The specification indicates on page 60, lines 13-16, that the SSR analyses were conducted at Celera AgGen, and on page 63, at the bottom of Table 6, that primers used in the analyses are also from Celera AgGen. However, without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

Applicant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Applicant argues that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Applicant argues that any of the U.S. patents issued on hundreds of different corn plants could be used to produce an F1 hybrid plant having I390185 as one parent, and each of these would share the genetic complement of I390185 (Appeal Brief, paragraph bridging pages 13-14 and page 14, 1st full paragraph).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from I390185, which

determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprises one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and the combined effects of multiple genes determine quantitative traits. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from I390185 alone, with the phenotype of the hybrid progeny. Thus, the deposit of I390185 seeds and the recitation of some phenotypic characteristics of corn plant I390185 is not sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing I390185 with a second, distinct corn plant. Applicant would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of I390185 was deposited, it would not have been enough to describe its full genome.

Applicant returns to the genetic marker data, alleging that the Action (presumed to be the Office action mailed June 30, 2003) attempts to downplay the significance of the genetic marker data in the specification, that no effort was made to show that any substantial number of marker loci actually are shared by other plants (response,

paragraph bridging pages 14-15). However, it remains that if other corn plants possess the SSR markers named in Table 6, then this criterion cannot be used to distinguish the claimed plants from unrelated corn plants. Applicant argues that these "other" plants are not claimed, so this is irrelevant to written description (response, paragraph bridging pages 14-15). However, Applicant is arguing that these SSR markers can identify the half of the hybrid's genome that was inherited from I390185. If other, unrelated corn plants also possess these markers, then this criterion does not distinguish the claimed hybrid seeds and plants from unrelated corn plants. Also, the specification does not mention anything concerning the traits expressed by the other corn plants named in Table 6, and how similar those traits are to the combination of traits expressed by I390185. Is a comparison to only two inbreds sufficient to establish that the sets of SSR and isozyme markers in Tables 6 and 8 can distinguish a corn plant as having I390185 as a parent from those that do not? Further, the specification fails to correlate any function, or trait, expressed by I390185, or the claimed hybrids, with any of the markers.

Applicant argues, regarding the availability of genetic markers or the primers used to detect the markers, that the service used to detect SSR markers is commercially available to the public, that SSR and other genetic marker systems that are well known may potentially be used, as described in the specification on pages 59-60 (response, paragraph bridging pages 14-15). However, that the service used to detect SSR markers is currently commercially available is not a guarantee that it will remain so for the life of a patent issuing from the application. Further, the specification at pages 59-60 only provides a general discussion of other types of genetic markers, and does not describe any actual markers possessed by corn plant I390185.

Applicant next argues, in response to the previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown, that the Examiner's position misses the point that Applicant has gone one step further by describing the claimed hybrid plants at the genetic level. Applicant asserts that a better description could not be made than at the genetic level (response, page 15, 1st full paragraph). However, again, Applicant is attempting to describe the claimed hybrids by only half of their genome. Applicant has deposited I390185 seed and, by extension, the I390185 genome, since the cells of the I390185 seed contain the I390185 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by I390185. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have less than one-half of the traits exhibited by I390185.

The specification also provides the names of loci of many SSR and isozyme markers in the genome of I390185. However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I390185, and therefore the claimed hybrids. Further, while I390185 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I390185, have been deposited.

Applicant continues, arguing that the law makes no distinctions regarding the manner in which applicant chooses to describe claimed compositions (response, paragraph bridging pages 15-16). However, the Examiner has not limited Applicant to describing the claimed invention in any specific manner. Applicant argues that the genetic complement of parent plant I390185 that will be comprised in the claimed hybrid plants has been described by way of the SSR and isozyme genetic marker profiles in Tables 6-9 (response, paragraph bridging pages 15-16). However, as discussed above, while loci where these markers are located are identified, the sequences of the markers, or of primers used to locate them, are not described, nor are any functions of any alleles that may be associated with the markers described.

Applicant repeats the argument that a further description of the claimed hybrid plants is provided in the specification by way of hybrid 0004555, and believes that this plant is representative of all hybrids produced using I390185 as one parent, each of which comprise the genetic complement of the parent corn plant (response, page 16, 1st full paragraph). Applicant argues that Table 4 provides performance comparisons of 0004555 with other hybrid varieties (response, page 16, 1st full paragraph). However, all of the claimed hybrid plants would not have the same performance characteristics as 0004555. Applicant argues that the information of Table 4 combined with the morphological traits in Table 5, the SSR and isozyme marker profiles in Tables 8 and 9, and the description of I390185 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter (response, page 16, 1st full paragraph). However, again, hybrids that do not share both of the same parents will not have the same combination of traits. The morphological traits in Table 5 and the performance of hybrid

0004555 cannot be extended to any other hybrid plant, and are not representative of all hybrids produced using I390185 as one parent.

Regarding claims 27-30, drawn towards corn plant I390185 containing single locus conversions: Applicant appears to be arguing that the specification describes such plants, simply because the definition of "single locus converted plants" provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I390185 in addition to the characteristics conferred by the single locus transferred. Applicant argues that because the specification indicates that the claimed plants possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]", that they have more than adequately described such plants (response, paragraph bridging pages 17-18). However, the specification does not describe any and all single locus conversion traits, nor the source of all of said traits. The traits conferred by the single locus may also change one or more of the traits expressed by I390185, depending on what the locus encodes. A single locus whose product confers male sterility, for example, will change a trait of inbred corn plant I390185, rather than adding an additional trait. Further, the descriptions of plants that express "essentially" all of the "desired" characteristics of I390185 are not described. The definition indicates that the plants possess the "desired" characteristics of I390185. The "desired," as opposed to the "undesired," traits are not described. Further, page 30 of the specification indicates that the goal of a backcross procedure is to alter or substitute a single trait in the original inbred, and that this is accomplished by modifying or substituting a single locus in the inbred with the desired locus in the other plant, while retaining essentially all of the rest

of the morphological and physiological constitution of the original inbred (lines 14-19). The claimed plants therefore may not still possess the combination of traits expressed by I390185, in addition to the trait conferred by the introduced locus.

Applicant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (response, paragraph bridging pages 17-18). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. The claimed genus reads on a multitude of I390185 plants further comprising a single locus conversion, and having a multitude of different morphological and/or physiological traits. As discussed, the specification does not describe plants that express only some or "desired" traits that are expressed by I390185, or how to distinguish such plants from I390185. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I390185. The claimed plant then may not express all of the "desired" traits of I390185. Such plants are not described by the specification.

In response to the issue raised in the previous Office actions that the claimed plants encompass introducing genes, or single loci, that have yet to be discovered, Applicant argues that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I390185 that is claimed (response, page 18, 1st full paragraph). However, if a gene has not been discovered or

isolated at the time the instant application was filed, Applicant cannot be in possession of a corn plant into which this gene was deliberately introduced. Furthermore, at least claim 30 explicitly recites undiscovered genes, since single loci that alone govern "yield enhancement" or "enhanced yield stability" have not been discovered.

Applicant continues, arguing that under the Examiner's reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a particular gene would be invalid because it would encompass corn varieties yet to be discovered (response, page 18, 1st full paragraph). In this example, however, there is only one genetic structure that is relevant, that of the particular gene, and only one function, that conferred by the product of the gene. A claim drawn towards a corn plant containing the gene may be described, if the structure and function of the gene is described. In the instant application, the invention encompasses corn seed I390185 and the plant produced by it. The deposit of the seed satisfies the written description requirement for the I390185 seed. A single locus that is substituted for another, or the introduction of another locus into I390185, would amend the structure and functions of corn plant I390185.

Applicant argues that the specification provides numerous examples of single locus traits, and point to passages from the specification (response, page 19 1st full paragraph to page 21, 1st full paragraph). While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that genes discussed therein have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated,

Applicant cannot be in possession of I390185 plants comprising this single locus conversion. The claims broadly encompasses plant I390185 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Applicant cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that Applicant is not being asked to identify each and every gene known to man by name, but to identify the types of single loci, that alone control a trait, that have been isolated in the prior art. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance. In the Office action mailed January 30, 2003 and June 30, 2003 it was suggested that the claims be amended to recite the types of single loci, not individual or specific loci names. Further, it is unclear how the introduction of a multitude of non-exemplified transgenes, encoding a multitude of proteins or enzymes or inhibitory RNA products which would be involved in a multitude of metabolic pathways resulting in a multitude of traits, would interfere with one or more of the traits expressed by corn plant I390185. Such interference would result in the production of a multitude of corn plants with a different collection of traits than the exemplified inbred.

Applicant argues that techniques for introducing single locus traits by genetic transformation were well known (response, page 21, 2nd full paragraph). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Regarding claim 31, Applicant argues that what is required to meet written description is that an Applicant show that he/she was in possession of the claimed

invention. Applicant argues that here a process is claimed, not a product of a process, and thus the steps of the process, not intermediate or final products, must be described (response, page 22, 1st full paragraph). However, comment No. 4 of 64 Fed. Reg. 71427, 71428 (1999) indicates that the suggestion to address process and product-by-process claims, to distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where the patentability rests in the steps of the process itself, has been adopted. The patentability of the method of claim 31 does not lie in the acts of the process, which are the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 includes steps in which undescribed hybrids (produced by crossing inbred corn plant I390185 with a second, different corn plant) are crossed with other corn plants. The suggestion that written description of process claims in which patentability depends on the compositions used in them, as opposed to those where patentability rests in the method steps, has been adopted into the Guidelines. Applicant cites *Vas-Cath, Inc. v. Mahurkar* in support of the argument that all that needs to be shown is that the Applicant is in possession of the claimed invention (response, page 22, 1st full paragraph). However, for the reasons discussed above regarding hybrids produced by crossing corn plant I390185 with a different corn plant, Applicant is not in possession of progeny plants produced in steps (a)-(d) of claim 31. Also note that steps (c)-(d) of claim 31 requires possession of plants beyond the F1 generation of plants, and that steps (b)-(d) indicate that progeny plants of any generation can be crossed with itself or a second plant. Because Applicant is not in

possession of such plants, Applicant is likewise not in possession of the methods of crossing the plants.

Applicant argues that corn breeding is well known to those of skill in the art, that without it there would not be commercial corn varieties (response, page 23, 2nd full paragraph). However, it is not in dispute that corn breeding is well known. Applicant argues that all of the steps of claim 31 are typical of the process used for the production of new corn varieties, save for the novelty of corn variety I390185 (response, page 23, 2nd full paragraph). The Examiner disagrees, and maintains that the progeny plants of steps (b)-(d) also need to be described, as written description of this process claim depends on compositions used in it, and not in the steps (the simple acts of conducting crosses and growing plants) of the process themselves.

7. Claims 27-30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed June 30, 2003. Applicant traverses the rejection in the paper received September 30, 2003. Applicant's arguments were fully considered but were not found persuasive.

Regarding the aspect of the rejection concerning the enablement of corn plants of variety I390185 comprising a single locus conversion, Applicant argues that no basis has been given to show that these references have any relevance to corn plants. Applicant argues that there is no support for the assertion that the cited references concerning

petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Applicant to show why this is not true. Applicant argues that it is the burden of the Office to support its rejections (response, page 24, 1st full paragraph and the paragraph bridging pages 24-25).

However, the rejection was supported with cited references. The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the I390185 plants comprising single locus conversions as currently claimed.

Further, the single locus may encode any product having any function, and can therefore affect the other traits expressed by I390185. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect the traits expressed by I390185. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of I390185, in addition to the trait conferred by the single locus.

In order to produce a single locus converted plant, a first inbred of interest is crossed with another "donor" inbred parent plant, which contains the trait that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological

and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent (specification, paragraph bridging pages 29-30). The claims, however, broadly encompass plants that comprise exactly the genome of I390185, further comprising just a single additional locus. While the introduction of a desired trait from one plant into another using crossing techniques is well known in the prior art, what is not clear is that a plant that has exactly the same genome as I390185 is recovered, in addition to the introduced single locus. The claims encompass such plants. The very first cross involves crossing I390185 to another plant and results in a plant that expresses traits that are very different from those expressed by I390185, due to the presence of the genetic material from the non-I390185 plant. It is not clear, despite repeated backcrossing with I390185, that a plant having the exact same genome of I390185 can be recovered (in addition to the introduced single locus), particularly in view of the genetic linkage of multiple genes conferring multiple additional traits, as established by the cited references. The specification attempts to address this by indicating that "essentially" all of the "desired" morphological and physiological traits of an inbred are recovered, in addition to the transferred single locus (page 29, lines 20-24). However, the claims are directed to exactly plant I390185 further comprising the single locus.

8. Claims 1, 2, 5, 7-10, 12, 13, 15, and 17-23 are allowed. Claims 3, 6, 11, 14, 16, 24, 25, and 27-31 are rejected.

Proposed Claim Amendments

9. The following claims are proposed, to replace pending claims 16 and 27-30. Regarding the proposed claims 32-41, directed towards methods comprising transforming corn plant I390185 and plants produced by the methods: the methods are considered acceptable because they indicate the traits that would be affected by the transgene (a single locus), or it recites the types of transgenes that are intended to be introduced into the plant. Of course, Applicant is not limited to only those traits mentioned in the proposed claims. Any trait may be recited, provided that there is written descriptive support in the specification and the prior art teaches that genes or single loci that affect such traits have been isolated. It is again noted that the Examiner is not requiring that the claims recite the actual names of any specific genes. Regarding the proposed claims 42-46, drawn toward a method of introducing a desired trait into the inbred plant of the invention using backcrossing techniques (which would result in plants comprising a single locus conversion, to use the terminology of the instant application), and the plants produced by the method: the proposed method claim is considered acceptable because it 1) indicates the types of traits that are contemplated, and 2) indicates that, after the inbred plant of the invention is crossed with a plant that contains the desired trait to be transferred, the progeny plant is to be backcrossed and selected at least five times, to ensure that undesirable genetic material from the donor plant is lost and that the resultant plant will also recover all of the traits of the original plant that are taught in Table 3 of the specification. It is important that the resultant plant retain the traits recited in Table 3, as it is this combination of traits that make inbred corn plant I390185 free of the prior art. Note that the proposed method claim does not require the recovery of I390185 traits that

are absent from Table 3, and therefore does not require that the resultant plant express all of the morphological and physiological traits of corn plant I390185. The method of the proposed claim results in a plant that expresses the traits of I390185 recited in Table 3, in addition to the introduced trait.

32. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 5 with a nucleic acid molecule that confers male sterility.

33. A male sterile corn plant produced by the method of claim 32.

34. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers herbicide resistance.

35. An herbicide resistant corn plant produced by the method of claim 34.

36. The corn plant of claim 35, wherein the transgene confers resistance to an herbicide selected from the group consisting of glyphosate and phosphinothricin.

37. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers insect resistance.

38. An insect resistant corn plant produced by the method of claim 37.

39. The corn plant of claim 38, wherein the transgene encodes a *Bacillus thuringiensis* endotoxin.

40. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers bacterial, fungal, or viral disease resistance.

41. A disease resistant corn plant produced by the method of claim 40.

42. A method of introducing a desired trait into corn inbred line I390185 comprising:

(a) crossing I390185 plants grown from I390185 seed, representative seed of which has been deposited under ATCC Accession No. PTA-4493, with plants of another corn line that comprise a desired trait to produce F1 progeny plants, wherein the desired trait is selected from the group consisting of male sterility, herbicide resistance, insect resistance, fungal disease resistance, bacterial disease resistance, and viral disease resistance;

(b) selecting F1 progeny plants that have the desired trait to produce selected F1 progeny plants;

(c) crossing the selected progeny plants with the I390185 plants to produce backcross progeny plants;

(d) selecting for backcross progeny plants that have the desired trait and traits of corn inbred line I390185 listed in Table 3 to produce selected backcross progeny plants; and

(e) repeating steps (c) and (d) four or more times in succession to produce selected fifth or higher backcross progeny plants that comprise the desired trait and all of the traits of corn inbred line I390185 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

43. A plant produced by the method of claim 42, wherein the plant has the desired trait and all of the traits of corn inbred line I390185 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

44. The plant of claim 43 wherein the desired trait is herbicide resistance and the resistance is conferred to an herbicide selected from the group consisting of: glyphosate and phosphinothricin.

45. The plant of claim 43 wherein the desired trait is insect resistance and the insect resistance is conferred by a transgene encoding a *Bacillus thuringiensis* endotoxin.

46. The plant of claim 43 wherein the desired trait is male sterility and the trait is conferred by a nucleic acid that confers male sterility.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638